



MISSOURI DEPARTMENT OF  
**HEALTH**

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Docket Management Branch  
Division of Management Systems and Policy  
Office of Human Resources and Management Services  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061 (HFA-305)  
Rockville, MD 20852

To Whom It May Concern:

**Equipment**

**21 CFR 900.12(b)(8)(i)**

***Application of compression. Effective October 28, 2002, each system shall provide: (A) An initial power-driven compression activated by hands-free controls operable from both sides of the patient; and (B) Fine adjustment compression controls operable from both sides of the patient.***

**Question:** With machines such as the GE 500T and 600T, which do not have a separate mechanism for compression fine adjustment, can tapping the foot pedal for fine adjustment of compression force meet the year 2002 requirement?

**Answer:** Yes. After receiving input from the National Mammography Quality Assurance Advisory Committee, comments from the public, and performing its own evaluation, FDA has determined that, with proper use, fine compression can be achieved with GE 500T and 600T units by tapping the foot pedal. While FDA recognizes that fine compression can be achieved using these mammography units, the specifics of the compression device require the technologist to pay additional attention during the application of compression. Where this causes clinical problems, facilities may want to consider modifying the compression device to allow for more consistent operator control. Facilities wishing to modify their units may contact their GE service representative for more information. Before a facility decides to modify the compression device, the facility should assure itself that the unit meets all the other new requirements (AEC performance, maximum compression force, focal spot condition and radiation output) that go into effect on October 28, 2002.

**RE: COMMENT ON GUIDANCE DOCUMENT #4—*Fine Adjustment compression***

I have concerns regarding the fine tune compression usage on the G.E. 500T & 600T units among other things. I think it is stretching the abilities of these old units. Tapping on the foot pedal is **not** fine tune compression. I am a technologist and my experience with these units does not allow a smooth compression in the first place and is very jerky. The problem I have experienced with these units is when a small amount of compression is applied and you let up on the pedal, the compression paddle still lowers on its own. I am assuming G.E. has addressed this issue when you are talking about an adjustment to the unit. When discussing this with other technologists they still have told me there would be much better

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control if the fine tune was manual and could be regulated more carefully. I really don't think the physicians who own these units realize how the improvements of newer models allows much more even compression and are much more stable. The paddles on these units jiggle so it is difficult to get good compression on them whether there is fine tune done manually or automatically.

Another concern I have on these units are the buckys. These units are old and the buckys have seen better days. In other words, déjà vu with the old Ausonics mammography units. G.E. is not making any new parts for these units, they don't sell them anymore. My experience for many owners of these units is that they cannot get a new bucky for their unit if the old one is broken. They will only get a re-manufactured one and that is not a guarantee that your problem with grid lines is going to go away. One particular facility I am thinking about received their new bucky because they were having problems with grid lines all over their films. Now they have grid lines sporadically in spots on the films instead of all over. They are still using this unit, this is the best they can get. Also, if your large bucky starts to have problems it is not available to correct this problem because G.E. does not have any large buckys to replace them with. Then you have the issue of passing your accreditation process. It is costly to go through this and if you fail twice you have spent all of this money, only to find out your unit is not good enough to produce high quality mammograms and the unit should be replaced.

The older models also do not have the safety factor of double exposing the patient. In the newer models, if a cassette has been exposed it will not let you take another exposure until that film has been removed. If you look at repeat analysis on these units, you will find this to be an issue.

Our technology has moved us into a direction that produces high quality films for mammography because the newer units allow us to use different target and filter combinations. Because they can only be used in the moly/moly setting they have a difficult time penetrating a very dense breast tissue in some cases. I believe the 500T & 600T units have served their purpose, but it is time for them to retire and move in the direction mammography continues to go. Please consider all of the problems connected with these units not just the fine-tune compression.

Sincerely,

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